

RECEIVED
U.S. PATENT AND TRADEMARK OFFICE
JUN 2 2000
EXAMINER 16000900

1. Claims 5-8 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by Cain *et al.* (WO97/18320);
2. Claims 13-17 stand rejected under 35 U.S.C. §103 as allegedly being obvious over Cain *et al.* (WO97/18320); and
3. Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cain *et al.* (WO97/18320), further in view of Pariza *et al.* (US Pat. No. 5,017,614).

Applicants believe that the following remarks traverse the Examiner's rejection of the claims. None of these references, alone or in combination, teach each element of the claims. Prior to considering the rejections, all of which are repeated from the previous Office Action, Applicants wish to address the Examiner's failure to consider the Declaration of Mr. Asgeir Sæbo. This failure is central to each of three rejections above.

In response to the previous office action, Applicants submitted a Declaration from Asgeir Sæbo which establishes that the compositions of Cain et al. necessarily included the 8,10 and 11,13 isomers of CLA. In response to the Sæbo Declaration, the Examiner states the following:

In response to applicants' arguments that Mr. Sæbo's experiments show that fatty acid composition obtained by Cain would comprise significant amount of 8,10; 11,13 and other isomers, note Applicant generated data, proffered to obviate prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. It is well settled patent law "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and , therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight. In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v Coe, 147 F.2d 568, 64 USPQ 359.

For the following reasons, Applicants respectfully submit that the Examiner's reliance on this standard is unfounded.

In re Michalek is in conflict with current PTO practice

The decision relied on by the examiner is more than 50 years old. While this case has not been directly overruled, it is in conflict with current case law and PTO practice. In particular, the Examiner's failure to accord the proper weight to the Sæbo Declaration does not conform with proper patent practice according the Manual of Patent Examining Procedure (MPEP). The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.¹

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is

¹ MPEP §§2144.08; emphasis added).

a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.²

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.³

Accordingly, even if the Examiner had established anticipation or a *prima facie* of obviousness in the preceding Office Action (and Applicants contend that he did not), the Examiner must respond to the information presented in the Declaration. The above directions of the court and the PTO state that the evidence **must be considered**. These directions do not categorize evidence according to whether it is developed by interested or disinterested parties and do not state that evidence developed by the inventor **may be ignored**. Indeed, the Examiner must start over and reconsider the entire anticipation or obviousness analysis. Instead of following this proper practice, the Examiner simply decided to ignore the Sæbo Declaration and rely on the reasons for rejections set forth in the prior office action. **There was no reweighing of the merits by the Examiner.**

The Evidence Presented in the Declaration is Not Failure Evidence

The Examiner has attempted to ignore the evidence provided by Applicants by relying on *In re Michalek* and characterizing the evidence as a failure. To the contrary, the evidence presented by the Applicants is not a failure to repeat the results of Cain et al. Cain et al. is **silent** as to the presence of the 8,10 and 11,13 isomers. The only way the Applicants results could be considered to be a failure is if Cain et al. affirmatively stated that the isomers were

² *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

³ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

not present and then Applicants failed not to produce the isomers. This is not the present situation. Applicants results supplement the teachings of Cain, and do not contradict them.

In particular, the Applicants followed the exact instructions of Cain and analyzed the product. The Applicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by Cain. The Examiner apparently places weight on the fact Cain is silent as to the presence of other isomers:

"Cain et al. do not expressly teach what the remain 36.2 percent of the fatty composition are. However, nowhere in Cain states that "conjugated linoleic acid" are exclusively for c9,t11; and t10,c12 isomers. Any new definition of "CLA" would be improper."

This statement along with the statement regarding Applicant's improper interpretation of Cain et al. is misplaced and fails to rebut the evidence in the Declaration. Cain et al.'s silence concerning the presence of the isomers cannot be equated with the absence of the isomers, despite the clear evidence to the contrary. Indeed, the Examiner proposes a definition of "conjugated linoleic acid" that is found nowhere in Cain et al. In particular, Cain et al. does not specifically define CLA to include non-active CLA isomers. As noted by Mr. Saebo, the results presented in Cain:

"Do not mean that the other isomers were not present, as was found in my repeat of Cain. This discrepancy is explainable by the facts that 1) methods for the analysis of CLA compositions in 1996 were rather crude and 2) Cain may have simply chosen not to include non-active isomers when reporting their results. Improved methods for detecting the various isomers of CLA were not developed until well after the 1995 priority date of Cain. This fact is substantiated by Yurawecz *et al.* (attached at Tab 2), who state "the CLA products analyzed in this study were found to contain up to 12 geometric and positional CLA isomers. These findings are based on appropriate and improved analytical methodologies [including gas chromatography techniques] that have only recently been developed." (Yurawecz, p. 281). Thus, Cain et al. may not have conducted an analysis which could detect the isomers in questions. Consideration of Example 18 of Cain et al. supports this analysis. The inventors state that their compositions, produced by the method of Example 6, contained 63.8% CLA, of which

48.9% was the cis 9, trans 10 isomer and 51.1% was the trans 10, cis 12 isomer. This means that the inventors provide no analysis of the remaining 36.2% of their composition. The 8,10; 11,13; and trans-trans isomers that are discriminated against in the present invention and detected in my repeat of Cain could well have been present in this fraction.

Thus, the Examiner's conclusions regarding Cain et al. are rebutted by actual experimental evidence.

Other Evidence Establishes That Other Isomers Were Present

No chemical isomerization method has been described in the literature to date which does not produce a variety of isomers. Indeed, it is impossible to isomerize linoleic acid by the methods described in Cain without producing other isomers. Accordingly, it appears that Cain et al. simply failed to conduct an analysis for the other isomers present in the isomerized product.

This conclusion is supported by reference to Sugano et al., Lipids 33(5):521-527 (1998)(reference 47 in Form 1449 filed April 10, 2000, copy attached hereto for the Examiner's convenience). Sugano et al. isomerized linoleic acid conditions similar to those described by Cain et al. The conditions utilized in the two references are compared in following Table.

Cain et al.	Sugano et al.
50 g linoleic acid, 95% pure	50 g linoleic acid, 99% pure
Solvent: 290 grams ethylene glycol	Solvent: 290 grams ethylene glycol
Catalyst: 15 g NaOH	Catalyst: 15 g NaOH
Reaction time: 2 hours	Reaction time: 2 hours
Reaction temperature: 180° C	Reaction temperature: 180° C
Reaction atmosphere: Inert	Reaction atmosphere: Nitrogen

As can be seen, the reaction conditions were almost identical. However, the results are not. As noted on page 522 of Sugano, the resulting CLA preparation contained the following CLA isomers: 29.8% c9,t11/t9,c11; 29.6% t10,c12; 1.3% c9,c11; 1.4% c10,c12; 18.6% t9,t11/t10,t12; 5.6% linoleic acid; and 13.7% other isomers. In contrast to the simplified analysis presented in Cain et al., isomerization of CLA results in the production of many different isomers, not just the desired c9,t11 and t10,c12 isomers.

As further support for this fact, the Examiner's attention is respectfully directed to examples 1-4 of the instant application. These examples compare non-aqueous alkali isomerization under high or low temperatures and aqueous alkali isomerization under high or low temperatures. **The important fact to note is that each reaction, even the low temperature non-aqueous alkali isomerization reaction (Example 1, Table 6), produced a distribution of the expected isomers, not just the c9,t11 and t10,c12 isomers.** Thus, ample evidence supports the conclusion that the analysis of Cain et al. is either incorrect or incomplete. Cain et al. appear to have either not analyzed for the isomers or chosen not to present data pertaining to the other isomers in their analysis. This is understandable because at the time, the other isomers were not expected to have a biological effect. However, just because data on these isomers was not presented does not mean that they are not present. Indeed, the evidence establishes that they were necessarily present as a result of the reaction conditions used by Cain et al.

Having established that the compositions of Cain et al. necessarily contained trans,trans; 8,10; and 11,13 isomers of CLA, the various rejections can be considered.

1. Claims 5-8 Are Not Anticipated by Cain *et al.* (WO97/18320)

Claims 5-8 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by Cain *et al.* (WO97/18320). As established above, the compositions of Cain necessarily contained levels 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain et al. does not anticipate the claims.

Additionally, to the extent that the Examiner is relying on anticipation by inherency, that reliance is misplaced. The Federal Circuit has stated that inherency cannot be based upon information provided in the disclosed invention. Indeed, to establish inherency the prior art must have recognized at the time of the Applicant's invention, that the elements now at issue

were inherently present in the Examiner's reference. For example, in *Continental Can Co. USA v. Monsanto Co.*, the Federal Circuit held that:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

(*Continental Can Co. USA v. Monsanto Co.*, 212 USPQ 323 [CCPA 1981]; emphasis added).

Furthermore, "[i]n relying upon the theory of inherence, the examiner must provide a basis in fact/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (MPEP §2112, quoting, *In re Robertson*, 169 F.3d 743 [Fed. Cir. 1999]; emphasis original). Applicants again submit, that since the prior art at the time of Applicants' invention did not recognize compositions or methods of producing compositions comprising less than 1% of particular CLA isomers that the cited reference does not anticipate the presently claimed invention.

Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

2. Claims 13-17 Are Not Obvious Over WO97/18320

Claims 13-17 stand rejected under 35 U.S.C. §103 as allegedly being obvious over Cain *et al.* (WO97/18320). Applicants respectfully note that a *prima facie* case of obvious requires that all elements of the claims be present in the cited reference. As established above, the compositions of Cain necessarily contained levels 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain *et al.* does not render the claims obvious. Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

3. Claims 5-8 and 13-17 Are Not Obvious Over the Combination of Nilsen, Cain and Pariza

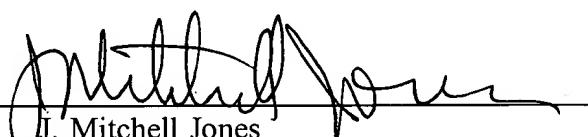
Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cain *et al.* (WO97/18320), further in view of Pariza *et al.* (US Pat. No. 5,017,614). The Examiner has failed to establish

a *prima facie* case of obviousness because the references, alone or in combination, fail to teach each element of the claimed compositions. Applicants note that as discussed in detail above, Cain et al. does not teach compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers or methods of obtaining such compositions. Likewise, Nilsen et al. provides no such compositions or methods. Indeed, Nilsen et al. **do not teach any method** at all for conjugation, they merely list CLA in a long list of fatty acids that may be useful in their invention. This fact is verified in paragraph 6 of the Saebo Declaration. Pariza et al. further fails to cure this deficiency. Accordingly, Applicants respectfully request that this ground of rejection be removed and the claims passed to allowance.

C O N C L U S I O N

All grounds of rejection of the Final Office Action of March 26, 2002, have been addressed, and therefore reconsideration of the application is respectfully requested. It is respectfully submitted that the claims are in condition for allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, the Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: May 27, 2003



J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
150 Howard St., Ste. 350
San Francisco, CA 94105
415-904-6500